

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant(s) : Andrea MARINELLO and Vittorio MARINELLO
Serial No. : 10/662,775
For : APPARATUS FOR THE INTRODUCTION OF A NEW SYSTEM FOR
THE TREATMENT OF MAXILLARY AND FRONTAL SINUSITIS
AND NEURITIS AND NEURALGIA OF THE TRIGEMINAL NERVE
Filed : September 15, 2003
Examiner : Isis A. Ghali
Art Unit : 1615
Confirmation No. : 2185

April 29, 2009

745 Fifth Avenue
New York, NY 10151

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellants request a Pre-Appeal Brief Conference for review of the Final Office Action mailed on November 13, 2008 (the "Office Action") in the above captioned application. Claims 1-33 are pending in this application, claims 1-12 and 31-33 have been withdrawn. No amendments are being filed with this request.

This request is being filed with a Notice of Appeal.

I) REASON FOR THE REQUEST

Appellant respectfully requests that the Panel review the rejection of claims 13-30 in this application. Claims 13, 15-25, and 27-30 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 2,262,711 to Ludwin ("Ludwin") in view of U.S. Patent No. 4,193,401 to Marinello ("Marinello"). Claims 14 and 26 were rejected under § 103(a) as

allegedly unpatentable over Ludwin in view of Marinello and U.S. Patent No. 5,248,540 to Friedman.

II) ARGUMENTS

Independent claim 13 recites:

A device comprising **a facial mask accommodated to allow unobstructed respiratory function of the nostrils and the mouth**, an inflatable elastic pad affixed to the facial mask and **a compress** fitted adjacent to said inflatable elastic pad, said **compress comprising a revulsive or cress having an active ingredient, wherein the device promotes the absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus** of a person in need thereof.

1) Numbered section 3 of the Office Action asserts that Ludwin teaches a medicinal nebulizer comprising a mask, medicament in a chamber contained in a sponge member, and pressure provided by a motor to vaporize the medicine to small pores of the sinus tract. Emphasis added. Appellants note that these features are not claimed in the pending claims. For this reason alone, Ludwin fails to teach the present invention.

2) Further, Ludwin fails to teach at least a facial mask **accommodated to allow unobstructed respiratory function of the nostrils and the mouth** as required by claim 13.

i) The invention according to Ludwin “embodies a mask...adapted to fit over the nose and mouth.” *Ludwin*, Column 1, line 55 – column 2, line 2.

ii) Ludwin teaches, “The invention is a mask...connected to a tube to a nebulizer, in which the medicament is contained.” *Ludwin*, column 1, lines 13-15.

(A) It is generally understood that a medical nebulizer volatilizes medicaments for application in the form of a vapor into respiratory passages through the mouth, the nose, or the mouth and nose. As such, a nebulizer temporarily and at least partially obstructs the respiratory function of the mouth, nose or mouth and nose.

iii) Accordingly, Ludwin does not teach **a facial mask accommodated to allow unobstructed respiratory function of the nostrils and the mouth** as required by claim 13.

3) Further still, Ludwin fails to teach a device comprising a **“compress comprising a revulsive or cress”** as required by claim 13.

i) A compress is “A soft pad...applied with pressure to a part of the body to control hemorrhage or to supply heat, cold, moisture, or medication to alleviate pain or reduce infection.” Dictionary.com. *Dictionary.com Unabridged (v 1.1)*. Random House, Inc. <http://dictionary.reference.com/browse/compress> (accessed: April 28, 2009).

(A) Ludwin’s mask “is preferably formed with a soft resilient contact member 5 which may be placed against the face.” *Ludwin*, column 2, lines 32-34. The reference is silent as to the contact member configured to supply medication to alleviate pain or reduce infection.

(a) Accordingly, Ludwin does not teach a **compress** as required by claim 13.

ii) A revulsive is an agent causing a revulsion or a “Counterirritation used to reduce inflammation or increase the blood supply to the affected area.” Dictionary.com. *Webster's Revised Unabridged Dictionary*. MICRA, Inc. <http://dictionary.reference.com/browse/revulsive> (accessed: April 28, 2009).

iii) A cress is “any of various plants of the mustard family.” Dictionary.com. *Dictionary.com Unabridged (v 1.1)*. Random House, Inc. <http://dictionary.reference.com/browse/cress> (accessed: April 28, 2009).

(A) Ludwin is silent on the medicament used in the medicinal nebulizer causing a counter irritation or increased blood supply to treat respiratory ailments.

(B) Ludwin is also silent as to the medicament including any plant of the mustard family, or that the medicament could include any type of plant matter in general.

iv) Therefore, Ludwin fails to disclose or render predictable the use of “**a revulsive or cress**” as required by claim 13

4) Additionally, Ludwin fails to teach at least a device that **promotes the absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus** as required by claim 13.

i) The object of the invention according to Ludwin is to provide a means for “readily volatilizing the medicament so that it may be applied in the form of a vapor” in a nebulizer. *Ludwin*, column 1, lines 40-43.

ii) Ludwin recognizes that “medicament applied in this manner [vapor]...penetrates the small pores of the sinus tract and is far more effective.” *Ludwin*, column 1, lines 36-39.

iii) Ludwin discloses a “medicament spraying apparatus.” *Ludwin*, column 4, line 19.

iv) As amply discussed above, Ludwin is directed to application of a vaporized medicament in a nebulizer. The function of a nebulizer is generally understood to be the vaporization of a substance to be inhaled through the mouth, the nose, or the mouth and nose. A nebulizer is not associated with absorption through the skin to bone.

v) Ludwin is silent on the absorption of any substance through skin and bones to underlying mucous membranes in a sinus cavity.

(A) Numbered paragraph 3 of the Office Action alleges that Ludwin teaches “to vaporize the medicine to small pores of the sinus tract.” While this may or may not be the teaching of Ludwin, “to vaporize the medicine to small pores of the sinus tract” *is not the same as absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus* as claimed. The instant invention indicates the active ingredient is absorbed into bones themselves, not vaporized into spaces merely formed in the sinus.

vi) Accordingly, Ludwin does not teach a device that **promotes the absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus** as required by claim 13.

5) In the full paragraph on page 6 of the Office Action, the Examiner recites, “US ‘401 [Marinello] is relied upon for the solely teaching delivering [sic] of medicament impregnated in a pad by force of inflatable elastic pump to the injured or inflamed part, and also for teaching means for securing the device to the head.”

i) Marinello is directed to treatment of the ocular organ and central nervous system with no suggestion of suitability for treating bone beneath the skin.

6) Page 9 of the Office Action relies upon Friedman to teach the treatment of sinus dysfunction with allyl isothiocyanate.

i) Accordingly, Marinello and Friedman fail to correct the deficiencies found in Ludwin as enumerated above.

For at least the foregoing reasons, because Ludwin fails to disclose or render predictable **a facial mask accommodated to allow unobstructed respiratory function of the nostrils and the mouth, a compress...comprising a revulsive or cress...wherein the device promotes the absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus**, Appellant respectfully submits that independent claim 13 patentably distinguishes over Ludwin. Nothing in Marinello or Friedman cures the defects in Ludwin.

CONCLUSION

In view of the foregoing remarks, Appellant's attorneys respectfully submit that claim 13 is patentable over the prior art. Claims 14-30, which depend from claim 1, are allowable as well.

Accordingly, reconsideration and withdrawal of the objections in the Office Action are respectfully requests, with prompt issuance of a Notice of Allowance.

Please charge any additional fees incurred by reason of this paper and not paid herewith, and credit any overpayment, to Deposit Account No. 50-0320.

Respectfully submitted,

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